

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0003]

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Certifier R. LEDESMA

Draft Guidance for Industry on Exercise-Induced Bronchospasm (EIB)—Development of Drugs to Prevent EIB; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Exercise-Induced Bronchospasm (EIB)—Development of Drugs to Prevent EIB.” The draft guidance is intended to assist sponsors in developing clinical trials for drugs that prevent EIB. The draft guidance addresses the types of trials that should be performed. It also discusses such issues as exercise testing, efficacy end points, and statistical analyses.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the Federal Register*]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Sandra L. Barnes, Center for Drug Evaluation and Research (HFD-570), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1050.

SUPPLEMENTARY INFORMATION:

I. Background

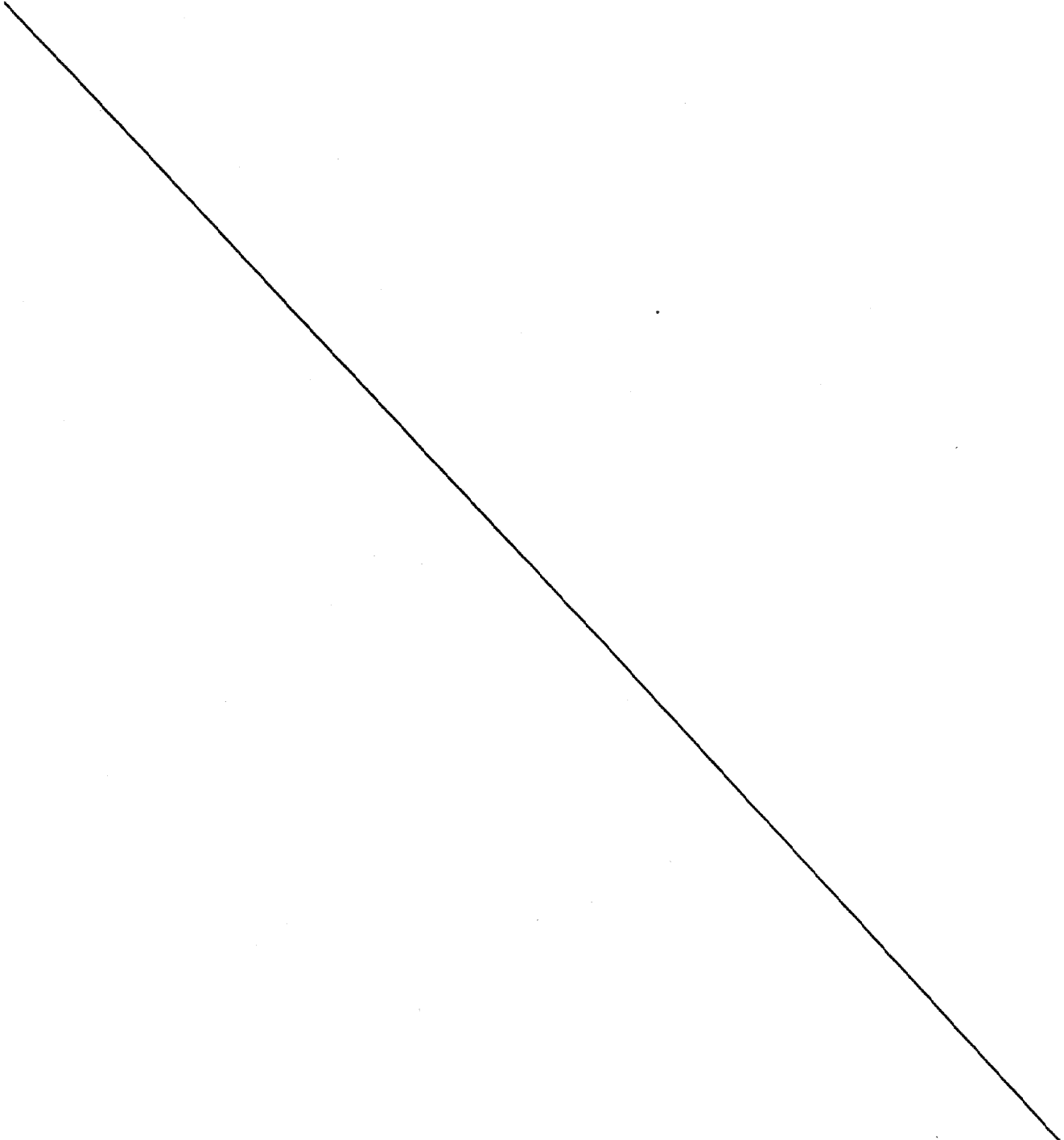
FDA is announcing the availability of a draft guidance for industry entitled “Exercise-Induced Bronchospasm (EIB)—Development of Drugs to Prevent EIB.” This draft guidance is intended to assist sponsors in designing clinical development programs to achieve an indication for the “prevention” of EIB. Drugs that are given chronically to control asthma may also lessen the propensity to develop EIB, as a general consequence of decreasing bronchial hyperreactivity. An important distinction is made, however, between such chronically administered drugs and shorter acting drugs that are given acutely to prevent or treat EIB. This guidance document is intended to provide trial design suggestions to help guide sponsors who are interested in developing drugs that are given acutely to prevent EIB.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency’s current thinking on EIB and the development of drugs to prevent EIB. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments

are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 1/30/02
January 30, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

LB
2-1402

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